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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,446	03/16/2004	Jeffery Carter	01597/1	1995

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Pfizer, Inc
5th Floor
575 Maryville Center Drive
St Louis, MO 63141

EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/801,446	CARTER ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 13-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>attached</u> . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. Applicant's election without traverse of group A claims 9-12 in the reply filed on Sept. 22, 2006 is acknowledged. Applicants' request to modify the restriction requirement dated Sept. 15, 2006 based on structural difference be withdrawn and be replaced by the examination of all the species for which applicants considered to be one inventive concept, has been acceptable.

Claims 9-12 are examined. Claims 1-8, 13-33 are withdrawn from consideration per 37 CFR 1.142(b).

2. Applicants attention is drawn to the non-rejoinable nature of claims 28-33 (group B).

In the restriction requirement, it was clearly delineated that:

"Applicants are reminded of propriety of process of use claims in consideration of the "reach-through" format, which is drawn to mechanistic, receptor binding or enzymatic functionality. Reach through claims are considered lacking of descriptive and enabling support from the specification. Thus, rejoinable process of use claims are those with particular disease named with efficacy support from the specification for treating the particular disease. **Failure to do so may result in a loss of the right to rejoinder.**"

In so far as claims 27-33 wherein applicants intend to be rejoined with the compound claims were any of the compounds found to be allowable, the 112 issue of the claims must be obviated. Please note that there is no evidence of record that the species of claims 9-11 would have obvious variation of potency as any other known COX-2 inhibitor and be able to treat *all COX-2 mediated disorders*. Especially, the state of the art indicated (see US 20030013739, US 20030114418 etc. not an exhausted listing) conditions related to and mediated through COX-2 are increasing continuously. A claim to all cox-2 mediated conditions would be considered a reach through to the continuous development of the field.

Only specific disorder disclosed in the specification, which have been documented at the time the invention was made that such specific condition has been treated by structural analogous compounds with similar potency as the instant compounds, may be presented for rejoinder were some of the instant compounds find neither anticipation nor obviousness over the art.

Art Unit: 1625

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. WO 98/47890.

Determination of the scope and content of the prior art (MPEP §2141.01)

Carter et al. '890 disclosed benzopyranyl compounds as COX-2 inhibitors. A detailed description of the genus coupled with well-exemplified species were disclosed.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instantly claimed species and the Carter et al. '980 reference is that the instant species are fully embraced by the generic description but are position isomers or analogous picking and choosing substituted compounds which are not particularly named by the examples of the reference.

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the instant species prima facie obvious over the reference **because** not only a detailed description of the generic concept was disclosed by the reference, the well exemplified compounds would guide one skilled in the art to pick and choose the instant claims. Particularly, on pages 32-52 multiple species of 6,8-disubstituted benzopyrans and 6,7,8-trisubstituted benzopyrans were disclosed. The very closely structural analogous compounds can be found by comparing:

Instant claim
Claim 9, p.748, 1st compound
Claim 10,, p.755, 1st compound
Claim 12, p. 744, 3rd compound
7-Br-phenoxy, 6-Cl,
position isomers

prior art '890
p.37, lines 27-28
8-Cl, 6-Cl-phenoxy

Art Unit: 1625

<u>Instant claim</u>	<u>prior art '890</u>
Claim 9, p.753 6-Cl, 8-OH-phenylethynyl generic OH/Cl equivalent optional choice	p.39, 1 st compound 6-Cl, 8-Cl-phenylethynyl
Claim 12, p.779, 2 nd -4 th compounds 6,7,8-tirsubstituted with generic alkyl/halo/OH equivalent optional choice	p.47, 1 st compound 6,7,8-trihalo substituted
Claim 9, p.749, last compound 6-Cl, 8-F-phenylethynyl F-substitution is generic optional	p.48, last compound 6-Cl, 8-phenylethynyl

Guided by the well exemplified compounds of Carter et al. '890 on pages 32-52 of the variation in position with broad spectrum of substituents, the instant particular species fully embraced by the generic disclosure of the prior art with modification in choosing equivalent optional substituents, or in position isomerism within the guidelines of the generic teaching rendered all the claimed compounds prima facie obvious. In absence of unexpected results, there is nothing unobvious in choosing some among many. In re Lemin 141 USPQ 814.

4. Claims 9-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,034,256 (cited on 1449). Although the conflicting claims are not identical, they are not patentably distinct from each other because the generic claim 1 of the issued patent fully embraced the instant species and the species claims with multiple variations of position isomers and equivalent optional choices of substituents rendered the instant specific species prima facie obvious. The same rationale as delineated in section 3 for the patent family of US 6,034,256 by WO 98/47890 is also applicable here and herein incorporated by reference.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Art Unit: 1625

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 9-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the elected claims 9-11 of copending Application No. 10/801,429 in view of claims 1-27 of US 6,034,256 and claims 1-2 of US 7,138,411.

This is a provisional obviousness-type double patenting rejection.

Determination of the scope and content of the copending claims

Both the instant claims and the copending claims are substituted benzopyranyl compounds with COX-2 inhibitory activity.

Ascertainment of the difference between the two sets of claims

The difference between the two sets of copending claims is that the instant claims are drawn to variation of substituents selected from halogen, unsubstituted or substituted alkyl, alkenyl, alkynyl, arylC₁₋₆alkoxy, heteroarylC₁₋₆alkoxy etc.; while the copending claims in addition to the same category of substituents, also included substituents such as aryloxy and heteroaryloxy etc. The claimed scope of US 6,023,256 encompassed the scope of variation of substituents selected from halogen, unsubstituted or substituted alkyl, alkenyl, alkynyl, arylC₁₋₆alkoxy, heteroarylC₁₋₆alkoxy etc. while the claimed scope of US 7,138,411 included the equivalent additional optional substituents such as aryloxy and heteroaryloxy etc.

Finding of prima facie obviousness—rational and motivation

One having ordinary skill in the art in possession of claims 1-27 of US 6,023,256 and claims 1-2 of US 7,138,411 would be in possession of all the variations of the analogous compounds for the COX-2 inhibitory compounds. Guided by the species claims and the well exemplified compounds of the specification of '256 or '411, one having ordinary skill would find the entire genus of claims for '256 or '411 delineated thus including the instant variation of species between claims 9-11 of the instant claims and claims 9-12 of the copending claims. Especially, applicants considered the species claims to be one inventive concept with request to withdraw the restriction among the compounds.

Art Unit: 1625

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1625

Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. WO 98/47890.

Determination of the scope and content of the prior art (MPEP §2141.01)

Carter et al. '890 disclosed species that has very close structural similarity with the instantly claimed compounds, see page 34, lines 10-11.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claimed species, i.e. 5th compound of claim 9, p.748, or claim 10, p.757 last compound, is that instead of 6-Cl, 7-methylbenzyl, the prior art compound has 6-Cl, 7-phenyl substitution. Generically, Carter et al. '890 taught that optionally substituted aryl and optionally substituted arylC₁₋₆alkyl are alternative choices for such substituents (see '890, claim 1, p.251 line 25-26 and p.252 line 11).

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art in possession of the generic teaching would be motivated to modify the phenyl substituent with a benzyl substituent because one skilled in the art would expect all the compounds disclosed by '890 to have similar activity. Especially, the prior art has been well exemplified with multiple species enabling and guiding one to the full scope of disclosure.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1625

Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al.

WO 98/47890 in view of Wermuth.

Determination of the scope and content of the prior art (MPEP §2141.01)

Carter et al. '890 disclosed species which has very close structural similarity with the instantly claimed compounds, see page 38, lines 23-26, p.39, lines 27-30, p.40, lines 11-12, p.49, lines 31-32, wherein thienyl, furanyl, chlorothienyl substituted 2-trifluoromethyl-chromene-3-carboxylic acid were exemplified with the thienyl, furanyl, chlorothienyl at 6, 7, or 8 positions.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claimed species, i.e. claim 10, 2nd to the last compound on p.757 or last two compounds of claim 12 on page 791, is that instead of thienylmethyl substitution, the prior art compound has direct substitution of theinyl. Generically, Carter et al. '890 taught that optionally substituted aryl and optionally substituted arylC₁₋₆alkyl are alternative choices for such substituents (see '890, claim 1, p.251 line 25-26 and p.252 line 11). Wermuth taught that thienyl moiety is a bioisostere of phenyl, thus, the generic teach between interchangeability of phenyl and benzyl is tantamount to a interchangeability between thienyl and thienylmethyl.

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art in possession of the generic teaching and the conventional knowledge of bioisosteric nature between phenyl and theinyl, would be motivated to modify the thienyl substituent with a thienylmethyl substituent because one skilled in the art would expect all the compounds disclosed by '890 to have similar activity and the interchangeability between phenyl and benzyl would be tantamount to render thienyl and thienylmethyl having the same expectation of having similar activity. Especially, the prior art has been well exemplified with multiple species enabling and guiding one to the full scope of disclosure.

8. Claims 9-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 (more particularly, col. 148, lines 1-2, 16-17) of U.S. Patent No. 6,034,256 (cited on 1449) in view of Wermuth. Although the conflicting claims are not identical, they are not patentably distinct from each other based on the same rational of finding prima facie obviousness as delineated supra in section 6 and 7.

9. Claims 9-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the elected claims 9-11 of copending Application No. 10/801,429 in view of claims 1-27 of US 6,034,256 in view of Wermuth based on the same rational of finding prima facie obviousness as delineated supra in section 6 and 7.

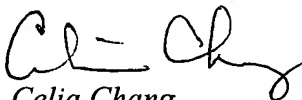
Art Unit: 1625

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Dec. 6, 2006


Celia Chang
Primary Examiner
Art Unit 1625